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(21) International Application Number: PCT/US98/11857 (22) International Filing Date: 9 June 1998 (09.06.98) (30) Priority Data: 08/954,155 20 October 1997 (20.10.97) US (71) Applicant: ABLATION TECHNOLOGIES, INC. [US/US]; Suite 100, 16980 Via Tazón, San Diego, CA 92127 (US). (72) Inventor: RYDELL, Mark, A.; 516 Turnpike Road, Golden Valley, MN 55416 (US). (74) Agent: NIKOLAI, Thomas, J.; Haugen and Nikolai, P.A., Suite 820, 900 Second Avenue South, Minneapolis, MN 55402-3325 (US).		(81) Designated States: AU, CA, JP, NZ, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Published <i>With international search report.</i> <i>With amended claims and statement.</i>
(54) Title: RADIOACTIVE AND/OR THERMAL SEED IMPLANTATION DEVICE <div data-bbox="266 1142 1318 1684" data-label="Image"> </div> (57) Abstract <p>An instrument for implanting radioactive and/or thermal seeds in body tissue for radiation and/or heat therapy, comprises a tubular hypodermic needle barrel (18) affixed to a pistol-grip shaped handle (12) which incorporates a reciprocally movable push rod (26) for stripping one such seed from a cartridge (28) containing a plurality of seeds, and advancing it to the end of the barrel. Actuation of a trigger in the pistol grip handle causes the barrel to retract relative to the push rod, causing the seed to be deposited in the channel in the body tissue created by the original puncturing thereof by the instrument's barrel.</p>		

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RADIOACTIVE AND/OR THERMAL SEED IMPLANTATION DEVICE**BACKGROUND OF THE INVENTION**

I. Field of the Invention: This invention relates generally to a surgical instrument useful in injecting thermal and/or radioactive seeds percutaneously into a body organ, and more particularly to an instrument of the type described which is effective to deposit such seeds in a desired axial alignment.

II. Discussion of the Prior Art: In the Paulus et al. Patent 5,429,583, there is described a seed of a ferromagnetic material which when injected into body tissue and subsequently exposed to an oscillating magnetic field produces localized heating of the tissue surrounding the seed for therapeutic purposes. For example, if the seeds are injected into the prostate gland, the heating may be used to shrink the prostate gland in addressing BPH. Radioactive seeds have also been injected into tumorous tissue so that the resulting radiation given off by the seeds will destroy the cancerous tissue.

Pending application Serial No. 08/864,486, filed May 28, 1997, describes a method for manufacturing a combination ferromagnetic/radioactive seed whereby both radioactive emissions and heat can simultaneously be applied to selected tissue structures.

When it is considered that to achieve optimum magnetic coupling between implanted ferromagnetic seeds and an external magnetic field producing coil, there must be appropriate alignment of the applied field to the implanted seeds, an instrument is required that can be used to inject such seeds so as to be aligned along a desired axis so that the patient's body can be appropriately oriented with respect to the external field coil.

The Scott Patents 4,402,308 and 5,242,373 describe medical instruments for percutaneously injecting radioactive seeds into tumorous tissue. Generally, they comprise a tubular hypodermic needle into which radioactive seeds may be fed. A push rod is provided for effectively

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forcing the seeds out of the distal end of the tubular needle. However, the device tends to be difficult to manipulate and often results in misaligned seeds following their implantation.

5 Thus, a need exists for an instrument that allows precise deposition of thermal/radioactive seeds into body tissue with the seeds being aligned with a predetermined axis.

SUMMARY OF THE INVENTION

10 In accordance with the present invention there is provided an improved apparatus for implanting ferromagnetic and/or radioactive seeds in body tissue. The apparatus includes a pistol-grip shaped handle having a spring-loaded trigger member supported in the handle. Projecting from
15 the pistol-gripped shaped handle is a tubular barrel having a proximal end, a distal end and a lumen extending therebetween. The distal end of the barrel is beveled and honed to facilitate penetration through the skin and into underlying body tissue. The pistol-gripped shaped handle
20 also supports a cartridge that holds at least one, but preferably a plurality, of ferromagnetic and/or radioactive seeds each of a predetermined length in axial alignment with the lumen of the barrel. Means are provided for advancing the bottommost one of the seeds out of the
25 cassette and along the lumen of the barrel to the distal end thereof. When the spring-loaded trigger is squeezed, the barrel is retracted in a proximal direction through a distance corresponding to the length of the selected seed causing it to be expelled from the lumen of the barrel and
30 deposited in body tissue in a channel that had resulted from the penetration of the barrel into the body tissue to be treated. Upon each actuation of the spring-loaded trigger, the barrel retracts one seed length, depositing yet another seed in the tunnel created by the penetration
35 of the barrel through the body tissue.

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DESCRIPTION OF THE DRAWINGS

The foregoing features, objects and advantages of the invention will become apparent from those skilled in the art from the following detailed description of a preferred embodiment of the invention in which like numerals in the
5 several views refer to corresponding parts.

Figure 1 is an exploded view of the seed injection device comprising a preferred embodiment of the invention;

Figure 2 is a side elevational view of the instrument
10 in assembled form;

Figure 3 is a top elevational view of the instrument;
and

Figure 4 is a partially sectioned side elevational view showing the internal working parts of the handle.

15 DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring to the drawings, the instrument comprising the preferred embodiment of the present invention is indicated generally by numeral 10 and is seen to include a pistol-grip shaped handle 12 having a proximal end 14 and
20 a distal end 16. Removably attached to the handle 12 and projecting outwardly from the distal end 16 thereof is a tubular barrel member 18, preferably fabricated from hypodermic needle stock. The internal lumen of the tubular barrel 18 has a diameter slightly larger than the diameter
25 of the seeds to be implanted.

The handle member 12 also supports a molded plastic guide 20 and visible in the view of Figure 3 there is a channel 22 in which is fitted a slide member 24 for reciprocal longitudinal movement as indicated by the
30 doubled-headed arrow in Figure 2. The slide 24 has a spring-loaded detent pin 25 affixed to a gripping knob 27 for engaging an aperture formed at a distal end of guide 20. The knob 27 must be raised to release the slide before it can be pulled rearward, i.e., proximally. An elongated
35 wire push rod 26 is affixed to slide member 24.

Supported atop the handle 12 is a seed cartridge 28 which when filled, contains a plurality of the seeds to be

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injected through the skin and into target body tissue to be treated.

Also supported in the pistol-grip shaped handle 12 is a spring-loaded trigger member 30. As will be explained in greater detail, the trigger 30 is operatively coupled to a threaded rod 32 that projects in the distal direction from the distal end 16 of the handle 12 and affixed to the distal end of the rod 32 is a U-shaped stop member 34.

Referring to Figures 1 and 4, the barrel 18 attaches to the handle 12 in a releasible fashion by means of a spring-loaded detent pin 36, the lower end of which is adapted to fit into an annular groove or recess 38 formed into the exterior of a tubular stud 40 that is affixed to the proximal end of the hypodermic needle barrel 18. Lifting of the detent pin 36 permits the hub and barrel to be withdrawn out through an opening formed through the distal end face 16 of the handle.

In the exploded view of Figure 1, there is shown one of a pair of alignment pins 40 that project outward in a distal direction from a face of the guide 20 and these alignment pins are designed to fit into mating bores (not shown) formed on a proximal edge 42 of the handle 12. When so inserted, the push rod 26 becomes longitudinally aligned with bores 44 and 46 (Figure 4) formed in the handle.

With continued reference to Figure 4, it can be seen that the seed cartridge 28 comprises a box-like housing containing a spring-loaded plunger 48 that acts against a plurality of rod-shaped seed implants indicated generally by numeral 50. The force of the spring 48 causes a bottommost one of the seeds 50 in the stack to become aligned with bores 52 and 54 formed in opposed parallel walls of the cartridge 28. The bores are dimensioned and positioned such that movement of the push rod 26 in the distal direction will strip the bottommost seed from the stack, forcing it through the lumen of the hub 40 and down the lumen of the tubular barrel 18.

With reference to Figure 3, the length of the push rod

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26 relative to that of the barrel 18 is such that when the slide 24 is advanced fully against the distal end 14 of the handle and two detent pin 25 falls into an aperture located near the proximal end 14 of the handle 12, the end of the push rod will be one seed length from the distal end of the barrel 18.

As can be seen in Figure 4, affixed to the trigger 30 is a flat spring metal pawl 56 that is adapted to engage the threads on the rod 32. A similar flat spring metal pawl 58 is affixed to the handle 12 and its free end is also adapted to engage the threaded rod 32.

In use, the physician will place a cartridge 28 containing a plurality of seeds 50 to be implanted into a receptacle in the handle. A tubular barrel 18 and a guide 20 with a push rod 26 will be selected as a matched pair, possibly with color coding or the like to insure that the two will be used together. The length thereof are selected to accommodate the physiology of the patient, especially the distance from the patient's skin surface to the target tissue. The barrel member 18 is inserted into the handle by lifting the detent pin 36 and then inserting the hub 40 through the distal face 16 of the handle until the detent groove 38 "clicks" with the detent pin. The selected guide and push rod assembly 20 corresponding to the barrel length is then plugged into the proximal side of the handle and the slide 24 is advanced in the distal direction so that the leading end of the push rod 26 passes through the aligned bores 52 and 54 in the cartridge, stripping off the bottommost seed and advancing it through the bore of the hub 40 and down the barrel 18. The barrel 18 is then advanced percutaneously into the target tissue where seeds are to be implanted.

Next, by holding the stop 34 against the patient's body or against a positioning template affixed to the operating table or a rectal ultrasound probe closely adjacent to the patient's anatomy where the seeds are to be injected and first squeezing and then releasing the trigger

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30, because the stop cannot itself move forward, the handle assembly and attached barrel will be caused to move proximally along the threaded shaft 32, resulting in the seed at the end of the barrel being released from the barrel and held in the puncture in the target tissue. The slide knob 24 may then be lifted to release it and manually retracted in its guide 22 and then again advanced to strip the next seed from the cartridge 28 and advance it through the barrel 18 to its distal end where again squeezing and releasing the trigger 30 will cause that next seed to be released near the tail end of the preceding seed in the same puncture wound.

This invention has been described herein in considerable detail in order to comply with the patent statutes and to provide those skilled in the art with the information needed to apply the novel principles and to construct and use such specialized components as are required. However, it is to be understood that the invention can be carried out by specifically different equipment and devices, and that various modifications, both as to the equipment and operating procedures, can be accomplished without departing from the scope of the invention itself. For example, the instrument can be further automated by incorporating pinch rollers driven by a battery driven by a small D.C. motor to actuate the reciprocal movement of the push rod 26 each time the trigger 30 is squeezed to thereby load a new seed in the hypodermic needle barrel 18.

What is claimed is:

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CLAIMS

1. Apparatus for implanting ferromagnetic and/or radioactive seeds in body tissue, comprising:

(a) a pistol-grip shaped handle having a spring-
5 loaded trigger member supported in said handle;

(b) a tubular barrel having a proximal end, a distal end and a lumen extending therebetween, the distal end of the barrel adapted to penetrate into the body tissue;

10 (c) a cartridge holding at least one ferromagnetic and/or radioactive seed of a predetermined length in alignment with the lumen of the barrel at the proximal end thereof;

(d) means for advancing the at least one seed
15 out of the cartridge and through the lumen to the distal end of the barrel; and

(e) means operative upon the actuation of the trigger member for retracting the barrel in a proximal direction by a distance corresponding to the predetermined
20 length of the at least one seed whereby the at least one seed is expelled from the lumen and deposited in the body tissue in a channel resulting from the penetration of the barrel into the body tissue.

2. The apparatus as in Claim 1 wherein the tubular
25 barrel comprises a hypodermic needle.

3. The apparatus as in Claim 1 wherein the means for advancing comprises a slide member affixed to the handle and a push rod disposed in the slide member for reciprocating longitudinal motion there along, the
30 operating length of the push rod being generally equal to the length of the barrel less the predetermined length of the at least one seed.

4. The apparatus as in Claim 3 wherein said cartridge comprises a rectangular box-shaped housing
35 adapted to contain a plurality of seeds stacked in parallel vertical relating to one another, the cartridge including a pair of aligned apertures in opposed parallel walls of

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the housing in alignment with the lumen of the barrel, the push rod being dimensioned to fit through the pair of aligned apertures during its reciprocal longitudinal motion.

- 5 5. The apparatus of Claim 1 wherein the means for retracting the barrel comprises a ratchet rod supported in the handle, the ratchet rod having a stop member at a distal end thereof with a pawl affixed to the spring-loaded trigger member for cooperating with the ratchet rod,
- 10 actuation of the spring-loaded trigger when the stop member abuts a body of a patient resulting in displacement of the handle and barrel in the proximal direction.

AMENDED CLAIMS

[received by the International Bureau on 17 September 1998 (17.09.98);
original claim 1 amended;
remaining claims unchanged (1 page)]

1. Apparatus for implanting ferromagnetic and/or radioactive seeds in body tissue, comprising:

(a) a pistol-grip shaped handle having a spring-
5 loaded trigger member supported in said handle;

(b) a tubular barrel having a proximal end, a distal end and a lumen extending therebetween, the distal end of the barrel adapted to penetrate into the body tissue;

10 (c) a cartridge holding at least one ferromagnetic and/or radioactive seed of a predetermined length in alignment with the lumen of the barrel at the proximal end thereof;

(d) means for initially advancing the at least
15 one seed out of the cartridge and through the lumen such that a leading end of the seed is at the distal end of the barrel; and

(e) means subsequently operative upon the actuation of the trigger member for retracting the barrel
20 in a proximal direction by a distance corresponding to the predetermined length of the at least one seed whereby the at least one seed is released from the lumen and deposited in the body tissue in a channel resulting from the penetration of the barrel into the body tissue.

25 2. The apparatus as in Claim 1 wherein the tubular barrel comprises a hypodermic needle.

3. The apparatus as in Claim 1 wherein the means for advancing comprises a slide member affixed to the handle and a push rod disposed in the slide member for
30 reciprocating longitudinal motion there along, the operating length of the push rod being generally equal to the length of the barrel less the predetermined length of the at least one seed.

4. The apparatus as in Claim 3 wherein said
35 cartridge comprises a rectangular box-shaped housing adapted to contain a plurality of seeds stacked in parallel vertical relating to one another, the cartridge including a pair of aligned apertures in opposed parallel walls of

STATEMENT UNDER ARTICLE 19

The replacement claim page 7 is intended to replace the originally submitted claim page 7. Claim 1 contains modifications intended to clarify and more concisely describe the invention, including differences from references cited. This claim is consistent with Claim 1 of the application to which this application claims priority.

The newly presented amended Claim 1 is believed to be within the scope of the invention described in the specification and drawings and, in addition to capturing the inventive concept more concisely, the amended claim enhances the definition over the references cited in category "X" and category "Y" in the International Search Report.

As amended, Claim 1 defines a device for implanting ferromagnetic and/or radioactive seeds in body tissue in which a push rod is used to initially advance a seed out of a cartridge and through a lumen of a tubular barrel, such that the leading end of the seed is at the distal end of the barrel. Then, subsequently, a means is operative upon actuation of a trigger member for retracting the barrel in a proximal direction by a distance corresponding to the predetermined length of the one seed, whereby the one seed is released from the lumen and deposited in the body tissue in a channel resulting from the penetration of the barrel into the body tissue. In the cited prior art, a trigger-operated push rod forces the seed out the distal end of the barrel. The trigger does not cause the barrel to retract.

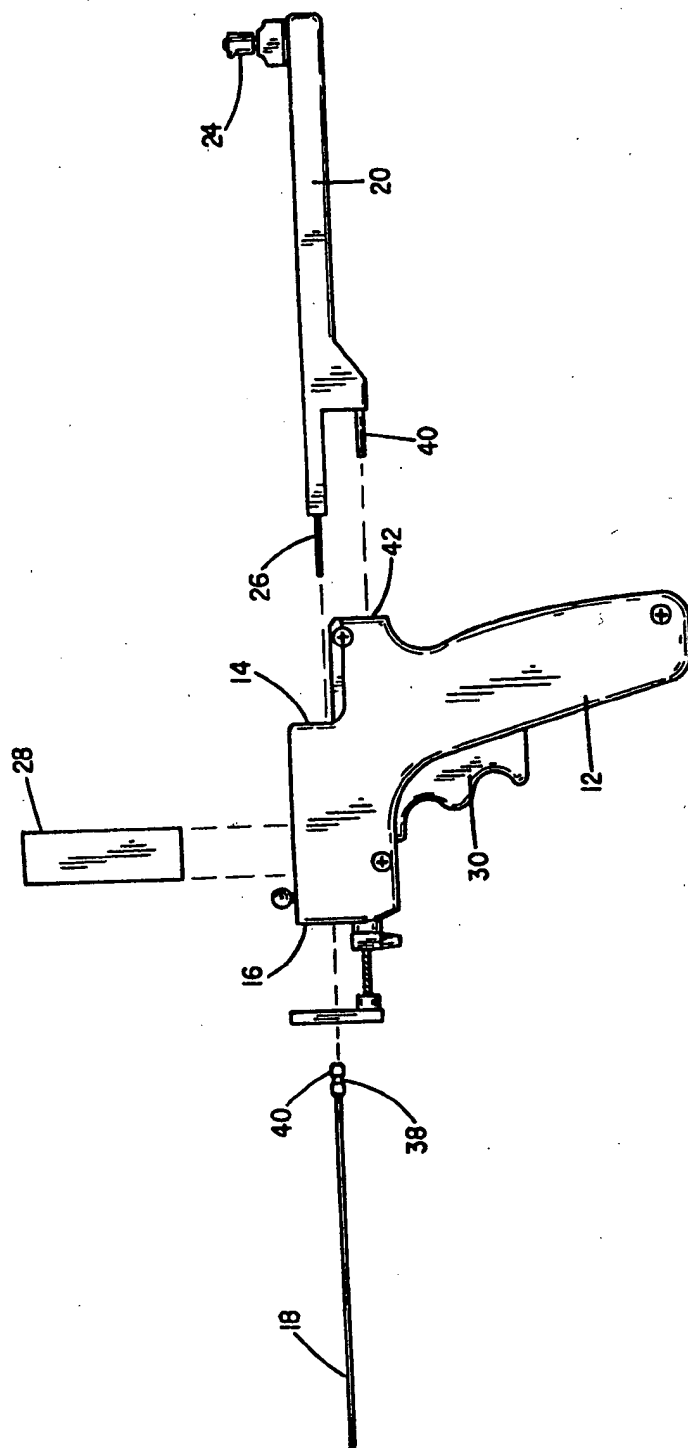


FIG. 1

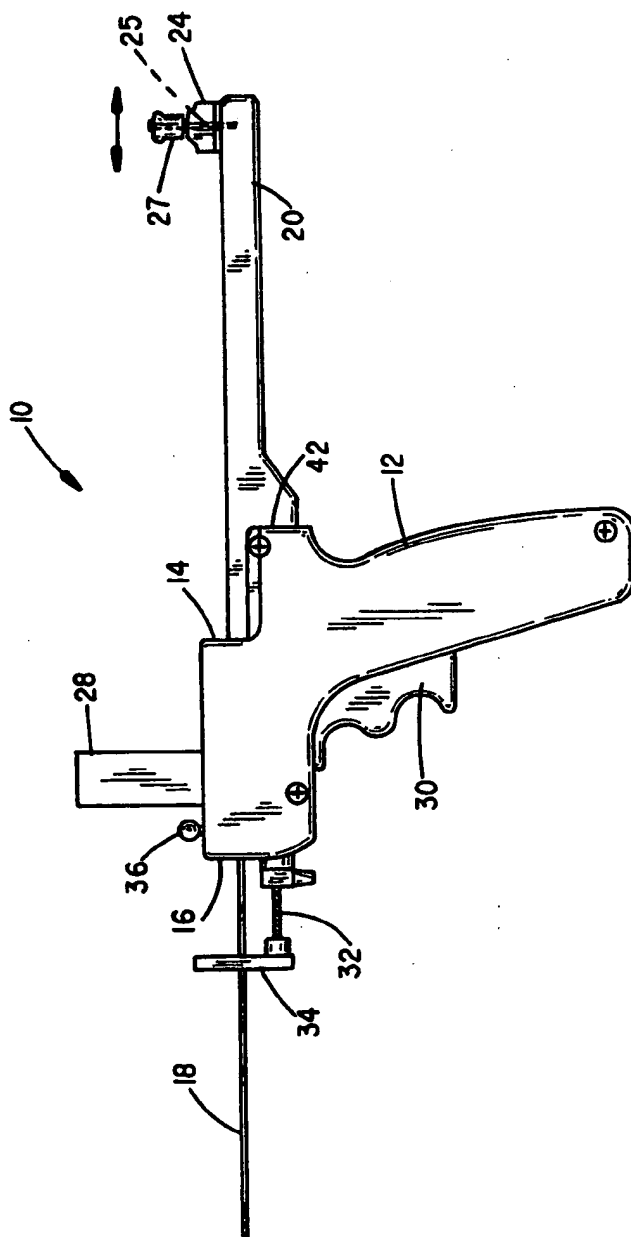


FIG. 2

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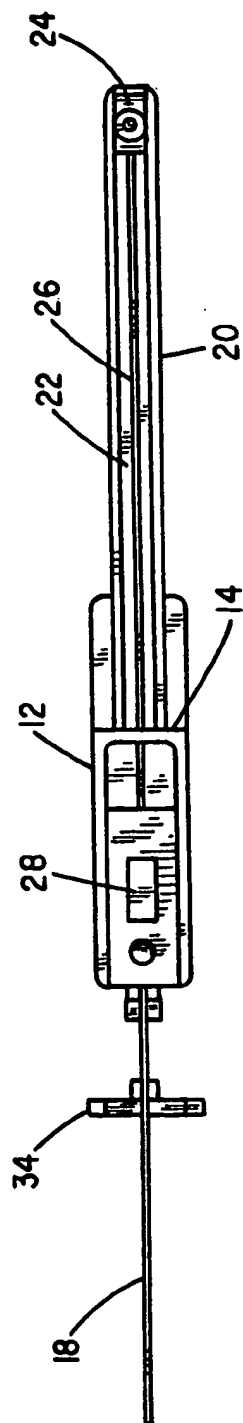


FIG. 3

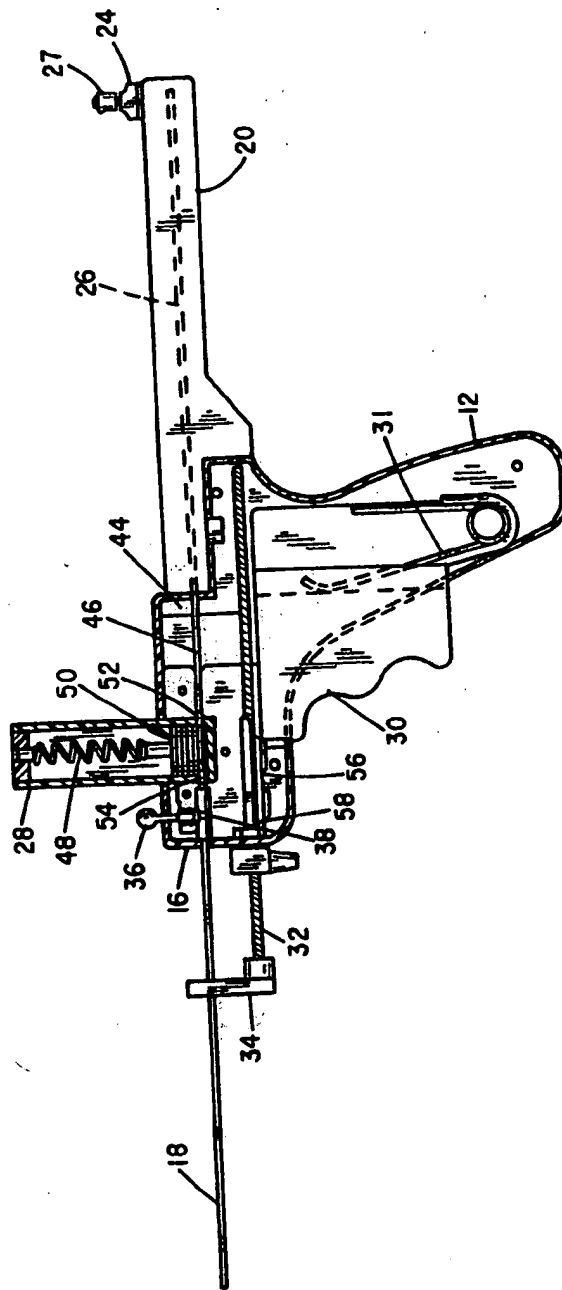


FIG. 4

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US98/11857

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61M 36/00

US CL :600/007

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 600/1, 3, 7; 604/57, 59, 61-64, 93, 95

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,135,493 A (PESCHKE) 04 August 1993, entire document.	1-4
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Y		5
Y	US 2,269,963 A (WAPPLER) 13 January 1942, entire document.	5

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Further documents are listed in the continuation of Box C.

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See patent family annex.

* Special categories of cited documents:	*T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
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L document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	*A* document member of the same patent family
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Date of the actual completion of the international search

10 AUGUST 1998

Date of mailing of the international search report

03 SEP 1998

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